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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,028	03/11/2004	Paul T. Gardiner	11411/11503	6725

26646 7590 12/19/2005

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,028	GARDINER ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58--97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

Pg. 4, line 6: "glycosphatidylinositols" should be "glycophosphatidylinositol".

Pg. 5, line 20: "bioflavinoids" should be "bioflavonoids".

Claims 68,77,97 are objected to because of the following informalities:

Claims 68,77,97 "inositiol" should be "inositol.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 78-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no disclosure in the Specification or claims as originally filed which describes a weight ratio of protein to carbohydrate of between about 4 to 1 and about 7 to 1 or a range of between about 3 grams and about 5 grams of carbohydrates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 58-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner et al. (US 2002/0006907) in view of Kuhrts (US 2002/0068365), Tabor (US Pat. 6,482,448), Hastings et al. (US 2001/0041187), Miller et al. (US Pat. 6,019,999), Ostlund et al. (US Pat. 5,550,166) and Shimizu et al. (US Pat. 6,004,926).

Gardiner et al. disclose a food supplement for increasing lean mass and/or muscle size containing lipoic acid, glutamine, arginine, ginseng, N-acetyl cysteine, carbohydrate, whey protein, inositol or d-pinitol which can be in the form of a liquid drink, capsule, pill or nutrition bar, which can be administered immediately following an exercise period (See entire reference, especially Paragraph 0031-0040, claims 1-43).

Kuhrts discloses that L-arginine enhance or modulate the release of nitric oxide and addition of glucomannan provides a sustained release effect of the L-arginine and bioequivalent agents and that the composition is effective in increasing exercise capacity (Paragraphs 0001, 0042, 0051).

Tabor discloses a dietary supplement which comprises a soy formulation and preferable comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder or liquid form (Column 6, lines 15-46).

Hastings et al. discloses a performance-enhancing supplement in powder form which can be mixed with juice, water, milk or any other drinkable non-alcoholic beverage with the recommended daily serving being about 26 grams to about 78 grams in the which the major ingredient is soy protein (Paragraphs 0006, 0007). It is disclosed that the supplement contains an amino acid premix of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and that glutamine promotes anabolic conditions in muscle cells, increase rate of protein and glycogen

synthesis, and indirectly promotes muscle growth, that alanine is an important source of energy for muscle tissue and that arginine is essential for optimal muscle growth and tissue repair (Paragraphs 0008-0010). It is disclosed that the supplement contains fat in the form of medium chain triglycerides with improve the absorption of the amino acids (Paragraph 0012) It is disclosed that the dietary supplement should include carbohydrate which supplies an energy source (paragraph 0014). It is disclosed that L-carnitine is added as it has been shown that athletes who supplement their diet with the same convert fat to energy more efficiently (Paragraph 0017). It is disclosed that individuals on an intense physical training regiment will gain optimal results at the higher levels of consumption whereas those on moderate or casual workout regimens will require less (Paragraph 0006).

Miller et al. discloses that for resistance-trained athletes the intake for protein should be approximately twice the normal RDI and that a preferred source of animal protein is dairy whey (column 1, lines 60-68, Column 2, line 1). A liposomal, ion-exchange whey protein is disclosed which is effective in increasing lean body mass, muscle mass with appropriate exercise and improving exercise performance (column 7, lines 46–60).

Ostlund et al. disclose that pinitol and derivatives and metabolites thereof are useful in nutritional composition for treating conditions associated insulin resistance including complications arising from athletic activity (Abstract). It is disclosed that inositol compounds improve insulin sensitivity (Columns 2, 3).

Shimizu et al. disclose a supplement containing protein, fat and carbohydrate which is ingested before, during and/or after exercise, particularly after the exercise immediately preceding a resting period, the protein is selectively taken up in the muscle tissue in the state where the process of protein assimilation is invigorated by the exercise, while the fat is used as

an energy source and consumed, with the resulting improvement in body composition contributing neatly to shape-up, body building, muscle increase and augmentation of the dynamic strength of muscles (Column 1, lines 55-68, Column 2, lines 1-64). Folic acid is disclosed as being used in the composition (Column 6, line 3).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of supplementing the diet of the diet of a human or increasing nitric oxide production a composition containing a protein, ginseng, N-acetyl-cysteine, glucomannan, folic acid and carbohydrate, where the weight ratio of protein to carbohydrate is between about 4 to 1 to 7 to 1 or the composition contains about 20 grams of protein and between about 3 and 5 grams of carbohydrate.

However, the prior art amply suggests the same as the combined teachings of the prior art discloses amounts of protein and carbohydrate which encompass or overlap the claimed amounts, the incorporation of ginseng, N-acetyl cysteine, glucomannan, folic acid, glutamine and compounds which mimic or enhance insulin activity such as pinitol, in compositions which can be in the form of powders which can be mixed with a diluant such as water, which can be administered to atheletes or immediately after exercise and that L-arginine promotes the release of nitric oxide. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the use of said composition would increase muscle mass and enhance athletic and/or exercise performance and cause the release nitric oxide in the body.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
December 12, 2005

SABIHA QAZI, PH.D
PRIMARY EXAMINER